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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,406	10/19/2006	Birgitte Holst Lange	LANGE6A	2286

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WASHINGTON, DC 20001-5303

EXAMINER

HA, JULIE

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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07/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,406	Applicant(s) LANGE ET AL.	
	Examiner Julie Ha	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,13-20,22,23,27-29,31,33-35,37,39,40,43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-3,5,6,13-20,22,23,27-29,31,33-35,37,39,40,43 and 44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Claims 4, 7-12, 21, 24-26, 30, 32, 36, 38 and 41-42 were cancelled in the Preliminary amendment filed on February 06, 2006. Claims 1-3, 5-6, 13-20, 22-23, 27-29, 31, 33-35, 37, 39-40 and 43-44 are pending in this application.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 5-6, 13-20, 22-23, 27-29, 31, 37, 39-40 and 43-44, drawn to a method for prophylaxis or treatment of cancer cachexia in an individual in need thereof comprising administration to said individual of a ghrelin-like compound or a pharmaceutically acceptable salt thereof.

Group II, claim(s) 33-35, drawn to a method for preventing or treating cancer, comprising administering to an individual in need thereof an effective amount of a ghrelin-like compound in combination with an anti-neoplastic treatment.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature recited in claim 1 is a method for prophylaxis or treatment of cancer cachexia by administering to an individual in need thereof ghrelin-like compound or a pharmaceutically acceptable salt thereof. In view of Bednarek MA (U.S. Patent # 6967237) reads on the claim. Bednarek patent teaches ghrelin analogs that can be administered to a subject that can be useful for a patient having a disease or disorder, or undergoing a treatment, accompanied by weight loss... cancer cachexia, AIDS, wasting cachexia... (see column 4, lines 26, 36-52). The reference further teaches a ghrelin analog having the structure $Z^1\text{-GSXF}(Z)_n\text{-Z}^2$. Therefore, the technical feature recited in claim 1 is not special, and unity of invention is broken. Furthermore, method for preventing or treating cancer is not treating or preventing the symptoms of cancer by

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the disease of growths of tumor. Therefore, cancer cachexia is one of the symptoms of cancer, and thus prophylaxis or treatment of cancer cachexia is treatment of the symptoms. A method for preventing or treating cancer is preventing or treating the disease itself. For example, see instant specification, paragraph [0163].

Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Different ghrelin analogs: at least 80% homologous to SEQ ID NO:1, at least 85% homologous to SEQ ID NO:1, at least 90% homologous to SEQ ID NO:1, at least 95% homologous to SEQ ID NO:1, at least 98% homologous to SEQ ID NO:1, Formula I, Formula II, Formula III, or Formula IV, SEQ ID NO:2, SEQ ID NO: 3,

Different disorder: catabolic or anorectic,

Different types of cancer: lung, pancreatic, liver, or GI tract,

Different anti-neoplastic treatment: radiotherapy or chemotherapy.

4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

5. If Group I is elected, the Applicant is requested to elect a single disclosed species of ghrelin analog, wherein all of the variables are encompassed in the analog to

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elect a single disclosed species (e.g., SEQ ID NO: 3 or Formula IV, wherein Z1 and Z2 are not present, X2 is Ser with $\text{CO}(\text{CH}_2)_6\text{CH}_3$ and X³ is Phe and n is 4), and the cancer is lung cancer. If Group II is elected, the Applicant is requested to elect a single disclosed ghrelin-like compound (i.e., analog) and an anti-neoplastic treatment.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-3, 5-6, 13-14, 27-29, 33-35 and 39-40.

The following claim(s) are generic: None.

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Different ghrelin analogs are patentably independent and distinct because they have different structures due to different amino acid content. For example, an analog having at least 80% sequence homology is not the same as an analog having at least 98% sequence homology. Furthermore, the formulas disclosed include variables and integers that make each structure different from each other. Further, search for one would not necessarily lead to the other. Catabolic and anorectic disorders are patentably independent and distinct because of different characteristics. Catabolic state is characterized by loss of muscle mass, accumulation of adipose tissue, bone demineralization and reduced capacity to regenerate tissue. Anorectic disorder is caused by anorexia nervosa. Further, search for one would not necessarily lead to the other. Different types of cancer are patentably independent and distinct because each cancer deals with different organ systems and cells (organs that the disease targets). For example, lung cancer (mainly due to cigarette smoking) is mainly in the lung and GI tract cancer is in the small intestine, large intestine or colon. Further, search for one would not necessarily lead to the other. Radiotherapy and chemotherapy are patentably independent and distinct. Radiation therapy uses ionizing radiation as part of cancer

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treatment to control malignant cells. Chemotherapy uses chemical substances to treat cancer such as alkylating agents, antimetabolites, anthracyclines, topoisomerase inhibitors and so on. Further, search for one would not necessarily lead to the other.

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

10. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

11. **Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.**

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Conclusion

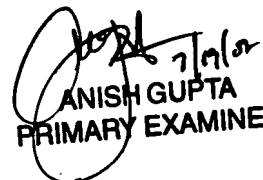
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982.

The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Julie Ha
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AU 1654


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